

DEC 0 6 2012

005-510 (k) Summary-807.92(c)

This 510 (K) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

SUMITTER INFORMATION A.

Company Name:

Prismatik Dentalcraft, Inc.

Company Address:

2212 Dupont Dr., Suite IJK

Irvine, CA 92612

Company Phone:

949-399-1940

Company FAX:

949-553-0924

Primary Contact Person:

Armin Zehtabchi, (949) 225-1234

Secondary Contact Person:

Marilyn Pourazar, (949) 225-1269

Date Summary Prepared:

November 28, 2012

B. **DEVICE IDENTIFICATION**

Trade/Proprietary Name:

Inclusive® Implant Bridge Framework

21 CFR Reference:

21 CFR 872.3630

21 CFR Common Name:

Endosseous Dental Implant Abutment

Classification:

Class II

Product Code:

NHA

Panel:

Dental

·C. IDENTIFICATION OF PREDICATE DEVICE

Trade/Proprietary Name:

Nobel /Procera Implant Bridge-K091848, Biomet

3i-CAM StructSure Overdenture Bars-K101582

DEVICE DESCRIPTION D.

Inclusive® Implant Bridge Framework attaches to implants. The Implant Bridge Framework is intended to be finished into a dental prosthesis using standard laboratory materials. The Inclusive® Implant Bridge Framework is customized by



following instructions and models specific to each patient.

The Inclusive[®] Implant Bridge Framework is made of titanium and shipped non-sterile. The Inclusive[®] Implant Bridge Framework will be attached with titanium screws.

E. INDICATION FOR USE

Indications for Use: The Inclusive[®] Implant Bridge Framework is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

The Inclusive Implant Bridge Framework is compatible with the following implant system: Nobel Biocare's Replace 3.5mm, 4.3mm, 5.0mm, and 6.0mm; Nobel Biocare's Branemark System 4.1mm; Nobel Biocare's Active 3.5mm and 4.3mm, Zimmer Dental Screw-Vent 3.5mm, 4.5mm, and 5.7mm; Biomet 3i Certain 3.4mm, 4.1mm, 5.0mm, and 6.0mm; Straumann Bone Level 4.1mm; Astra Tech OsseoSpeed 3.5mm and 4.5mm.

F. SUBSTANTIAL EQUIVALENCE

The Inclusive[®] Implant Bridge Framework is substantially equivalent to the Nobel /Procera Implant Bridge and Biomet 3i-CAM StructSure Overdenture Bars. The Inclusive[®] Implant Bridge Framework is substantially equivalent in indications for use, material, design and performance.



Comparison of Predicate Devices

Bridge Framework K091848 Overdenture Bridge Framework K091848 Overdenture Ti-6Al-4V ELI Ti-6Al-4V ELI Ti-6Al-4V ELI Alloy Alloy Alloy conforming to ASTM F 136 ASTM F 136 The Inclusive* The Nobel Procera The 3I Patient-Specific CAM StructSure* Implant Bridge is indicated for use as indicated for use as a pridge framework is indicated for use as a pridge framework in the treatment of partially or totally celentulous jaws for the purpose of restoring chewing function. The partially or totally or edentulous partially or totally celentulous jaws for the purpose of restoring chewing function. Precision-milled bars made of trianium. Precision-milled Precision-milled bars made of retenhological characteristics have been previously cleared for market (K091848). Precision-milled bars made of trianium. Precision-milled bars made of trianium materials have been previously cleared for market (K091848). Performance and technological characteristics have been previously cleared for market (K101822). The titanium materials have been previously cleared for market (K101828). Performance and technological characteristics have been previously cleared for market (K101848).	Elements of	Prismatik's	Nobel /Procera	Biomet 3i's CAM	Prismatik's	Riomet 31's
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G. PERFORMANCE DATA

The following FDA's Guidance Document "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments was used for the purpose of Implant to Abutment Compatibility. Various static and fatigue tests were performed by following the ISO 14801: 2007- Dentistry — Implants —Dynamic fatigue test for endosseous dental implants. All testing conducted met the acceptance criteria and evaluated the worst case scenario. Performance testing data indicated the compatibility, and the safety and the effectiveness of the proposed device which meets the mechanical properties. In addition, the sterilization tests were validated by following the ANSI-AAMI ST79-2006: Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Furthermore, the use of Titanium alloy as a material with acceptable performance for Inclusive Implant Bridge Framework is well documented in the dental literature.

H. COMPARISON OF TECHNOLOGICAL DIFFERENCES

There are no known technological differences between the Inclusive[®] Implant Bridge Framework and those of the predicate devices.







Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-002

December 6, 2012

Ms. Kathleen Dragovich
Manager, Regulatory Affairs / Quality Assurance
Prismatik Dentalcraft, Incorporated
2212 Dupont Drive, Suite P
Irvine, California 92612

Re: K120858

Trade/Device Name: Inclusive® Implant Bridge Framework

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II Product Code: NHA

Dated: November 16, 2012 Received: November 19, 2012

Dear Ms. Dragovich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

004-Indications for Use Statement

510 (K) Numbe	r (if known): To be deter	rmined					
Device Name:	Device Name: Inclusive® Implant Bridge Framework						
	rk in the treatment of par		mework is indicated for use as a y edentulous jaws for the purpose				
system: Nobel Branemark Syst Screw-Vent 3.5	Biocare's Replace 3.5mm em 4.1mm; Nobel Bioca mm, 4.5mm, and 5.7mm	n, 4.3mm, 5.0i re's Active 3.5 ; Biomet 3i Ce	ole with the following implant nm, and 6.0mm; Nobel Biocare's 5mm and 4.3mm, Zimmer Dental extain 3.4mm, 4.1mm, 5.0mm, and eseoSpeed 3.5mm and 4.5mm.				
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Prescription U	se: Yes 🛛 No 🗌	Over-the	-Counter Use: Yes 🗌 No 🔀				
(Part 21 CFR 8	01 Subpart D)	(Part 21 (CFR 807 Subpart C)				
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Concur	rence of CDRH, Office of	of Device Eval	uation (ODE) Susan Runner DDS, MA 2012.12.06 13:40:31				
	 D	Page 6 of 12	(Division Sign-Off) Division of Anesthesiology, General Hospital Infection Control, Dental Devices				
	•	~6v v vi 12	510(k) Number: K120 858				